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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/619,649	03/27/1996	RADOJE DRMANAC	ARCD:146/BOW	7575
<div>7590 04/07/2010</div> <div>MARSHALL O'TOOLE GERSTEIN MURRAY & BORUN</div> <div>6300 Sears Tower</div> <div>233 South Wacker drive</div> <div>Chicago, IL 60606-6402</div>				
EXAMINER				
FORMAN, BETTY J				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

08/619,649

Applicant(s)

DRMANAC, RADOJE

Examiner

BJ Forman

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 March 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 97 and 157-189 is/are pending in the application.
- 4a) Of the above claim(s) 176 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 97, 157-175 and 177-189 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SEA-3)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 15 March 2010 has been entered.

Status of the Claims

2. This action is in response to papers filed 15 March 2010 in which claims 97 and 166 were amended and claims 177-189 were added. All of the amendments have been thoroughly reviewed and entered.

The previous rejections in the Office Action dated 15 December 2009 are withdrawn in view of the amendments. Applicant's arguments have been thoroughly reviewed but are deemed moot in view of the amendments, withdrawn rejections and new grounds for rejection. New grounds for rejection are discussed.

Claims 97, 157-175 and 177-189 are under prosecution.

Claim Interpretation

3. Claims 183 and 489 are written using means-plus-function language. Therefore, the claims are evaluated under 35 U.S.C. 112, Sixth Paragraph. The MPEP § 2181-

2184 provides guidance for claim evaluation and examination under 35 U.S.C. 112,

Sixth Paragraph as set forth below:

The USPTO must apply 35 U.S.C. 112, sixth paragraph in appropriate cases, and give claims their broadest reasonable interpretation, in light of and consistent with the written description of the invention in the application. See *Donaldson*, 16 F.3d at 1194, 29 USPQ2d at 1850 (stating that 35 U.S.C. 112, sixth paragraph “merely sets a limit on how broadly the PTO may construe means-plus-function language under the rubric of reasonable interpretation.”). The Federal Circuit has held that applicants (and reexamination patentees) before the USPTO have the opportunity and the obligation to define their inventions precisely during proceedings before the PTO. See *In re Morris*, 127 F.3d 1048, 1056–57, 44 USPQ2d 1023, 1029–30 (Fed. Cir. 1997).

A claim limitation will be presumed to invoke 35 U.S.C. 112, sixth paragraph, if it meets the following 3-prong analysis:

- (A) the claim limitations must use the phrase “means for ” or “step for; ”
 - (B) the “means for ” or “step for ” must be modified by functional language; and
 - (C) the phrase “means for ” or “step for ” must not be modified by sufficient structure, material, or acts for achieving the specified function.
- (see MPEP § 2181(I)).

Claims 183 and 189 define “means to transfer separately....probe”. The claim meets the 3-prong analysis and therefore will be interpreted in light of the specification. The instant specification at page 42, lines 7-16 defines tools for adding probes as a pin array or multichannel pipet.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 183 and 189 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to an apparatus comprising a solid support comprising a plurality of sections and means to transfer....probes. Applicant has pointed to page 42 for support of the newly defined apparatus. While the specification (page 42, lines 7-16) defines tools for adding probes i.e. pin array or multichannel pipet, the specification does not define an apparatus comprising the newly claimed support & transport means. Furthermore, the specification does not suggest such a multi-component apparatus. Therefore the newly claimed apparatus appears to encompass new matter.

Additionally, the limitation, "means to transfer", is deemed new matter. While the specification (page 42, lines 7-16) defines tools for adding probes i.e. pin array or multichannel pipet, the specification does not define these tools as "means for transfer" so as to provide support for the newly claimed means as required by 35 U.S.C. 112, 6th paragraph.

The MPEP provide guidance regarding determining whether the specification provides a written description of the means-plus-function claims.

37 CFR 1.75(d)(1) provides, in part, that **“the terms and phrases used in the claims must find clear support or antecedent basis in the description so that the meaning of the terms in the claims may be ascertainable by reference to the description.”** In the situation in which the written description only implicitly or inherently sets forth the structure, materials, or acts corresponding to a means- (or step-) plus-function, and the examiner concludes that one skilled in the art would recognize what structure, materials, or acts perform the function recited in a means- (or step-) plus-function, the examiner should either: (A) have the applicant clarify the record by amending the written description such that it expressly recites what structure, materials, or acts perform the function recited in the claim element; or (B) state on the record what structure, materials, or acts perform the function recited in the means- (or step-) plus-function limitation. Even if the disclosure implicitly sets forth the structure, materials, or acts corresponding to a means- (or step-) plus-function claim element in compliance with 35 U.S.C. 112, first and second paragraphs, the USPTO may still require the applicant to amend the specification pursuant to 37 CFR 1.75(d) and MPEP § 608.01(o) to explicitly state, with reference to the terms and phrases of the claim element, what structure, materials, or acts perform the function recited in the claim element. See 35 U.S.C. 112, sixth paragraph (“An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.” (emphasis added)); see also B. Braun Medical, 124 F.3d at 1424, 43 USPQ2d at 1900 (holding that “pursuant to this provision [35 U.S.C. 112, sixth paragraph], structure disclosed in the specification is corresponding’ structure only if the specification or prosecution history clearly links or associates that structure to the

function recited in the claim. This duty to link or associate structure to function is the quid pro quo for the convenience of employing 112, paragraph 6.”); Medical Instrumentation and Diagnostic Corp. v. Elekta AB, 344 F.3d 1205, 1218, 68 USPQ2d 1263, 1268 (Fed. Cir. 2003)(Although one of skill in the art would have been able to write a software program for digital to digital conversion, such software did not fall within the scope of “means for converting” images as claimed because nothing in the specification or prosecution history clearly linked or associated such software with the function of converting images into a selected format.); Wolfensperger, 302 F.2d at 955, 133 USPQ at 542 (just because the disclosure provides support for a claim element does not mean that the USPTO cannot enforce its requirement that the terms and phrases used in the claims find clear support or antecedent basis in the written description). MPEM § 218(1V).

The specification does not provide clear support or antecedent basis for the claimed “means”. Applicant points to page 42 of the specification for support of the newly claimed means. However the passage merely teaches use of a pin array or multichannel pipet, but a “means for transfer” is not disclosed. The specification has been thoroughly reviewed for support, but none has been found. The specification does not describe or define corresponding structure(s) for the recited functions so as to clearly link structure to function as required under 35 U.S.C. 112, first paragraph.

If Applicant provides convincing evidence that the specification, as originally filed, inherently provides support, Applicant must either (A) clarify the record by amending the written description such that it expressly recites what structure, materials, or acts perform the function recited in the claim element; or (B) state on the record what

structure, materials, or acts perform the function recited in the means- (or step-) plus-function limitation (see above).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 97, 157-175, 177-182, 184, 186-187 are rejected under 35 U.S.C. 103(a) as being unpatentable over Southern et al (Genomics, 1992, 13: 1008-1017) in view of Kauvar (U.S. Patent No. 5,356,784, issued 18 October 1994) and/or Wang (U.S. Patent No. 4,618,475, issued 21 October 1986).

Regarding Claims 97, 157-158, 166-168, 177-182 and 186, Southern discloses a support comprising an array of four microchips, each having an array of oligonucleotide probes immobilized thereon (Fig. 3, figure legend, line 1). Southern teaches each array is in one of four quadrants on the surface (Fig. 3). The four-quadrant arrangement is encompassed by the physical separation because a quadrant defines a physical location of the surface. Assignment of an array to a quadrant defines a boundary between quadrants, the boundary being the point of physical separation. The reference specifically teaches that the arrays are physically separated, Southern does not specifically teach a physical barrier for keeping the arrays and/or probes in

corresponding arrays. However, physical barriers grooved and/or hydrophobic were well known in the hybridization art at the time the invention was made as taught by Kauver and Wang.

Kauver teaches an array of reaction regions on a solid support, each region having a plurality of ligands immobilized in the region wherein the regions are separated by a hydrophobic barriers (Column 7, lines 39-45) whereby reactions within the regions are defined thereby simplifying interpretation of assay results (Column 4, lines 37-58). Wang also teaches an array of reaction areas separated by hydrophobic barriers whereby cross-contamination is virtually eliminated and an "excellent appearance of the final product" is obtained (Column 4, lines 22-53).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the physical separation of Wang and/or Kauver to the multiple arrays of Southern. One of ordinary skill in the art would have been motivated to do so, with a reasonable expectation of success, for the expected benefit obtaining clearly defined assay results as is well known and routinely practiced in the art of bio-assays (Kauver, Column 4, lines 37-58 and Wang, Column 4, lines 22-53).

Regarding Claims 159 and 169, Southern discloses the support wherein the microchips are arranged in multiple rows and columns (i.e. two rows and two columns, Fig. 3). And Kauver teaches the arrays in an orderly design pattern" (Column 4, line 60) and Wang teaches the similar support comprising multiple rows (Fig. 1).

Regarding Claims 160 and 170, Southern discloses the support wherein the microchips are positioned for use with a multichannel pipette (Fig. 3). The arrays of

Southern are arranged in two rows of two columns. While Southern does not teach use of a multichannel pipette, the courts have stated that a claim containing a "recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus" if the prior art apparatus teaches all the structural limitations of the claim. *Ex parte Masham*, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987). Southern teaches the structural elements of the claim and therefore, teaches the support of Claims 160 and 170.

Regarding Claim 161 and 171, Kauver teaches the apparatus is used with labeled reagents and wash buffer (Column 5, line 55-Column 6, line 15). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the reagents used with the apparatus into a kit format for the well known benefits of kit convenience.

Regarding Claims 162 and 172, Southern teaches a 4 by 4 array but does not teach an 8 by 12 array. However, spotting probes in an 8 x 12 format (i.e. microtiter plate) was well known and routinely practiced in the art at the time the invention was made as taught by Kauver who further teaches that any convenient or orderly pattern are chosen based on convenience (Column 4, lines 58-64).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the 8 by 12 format of Kauver to the arrays of Southern based on desired format as taught by Kauver (Column 4, lines 58-64).

Regarding Claims 163 and 173, Southern discloses the support wherein the array of microchips comprises more than 256 probes i.e. each of the four microchips

has 256 probes. Hence, the support of Claim 97 has more than 256 probes per array as claimed.

Regarding Claims 164 and 174, Southern discloses the support wherein the probes are between 4 and 9 bases (Fig. 3).

Regarding Claims 165 and 175, Southern discloses the support wherein the probes are synthesized on the support (page 1009, left column). Southern does not teach light-directed synthesis. However, the courts have stated that "even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) see MPEP 2113. Because determination of patentability is based on the product and because Southern teaches the product, the process of making the product as recited in the claim does not define the product over that of Southern.

Regarding Claims 184 and 187, Southern teaches the support has duplicate arrays thereby providing arrays that are identical to other arrays, but different from others (Fig. 4 and accompanying text).

8. Claims 97, 157-175, 177-189 are rejected under 35 U.S.C. 103(a) as being unpatentable over Drmanac et al (Electrophoresis, 1992, 13:566-573) in view of Kauvar

(U.S. Patent No. 5,356,784, issued 18 October 1994) and/or Wang (U.S. Patent No. 4,618,475, issued 21 October 1986).

Regarding Claims 97, 157-158, 166-168, 177-182 and 186 Drmanac discloses a support comprising multiple microarrays (Fig. 4), each comprising an array of differing oligonucleotides immobilized thereon wherein the microarrays are separated from each other. The arrays illustrated in Fig. 4 clearly appear to be separated by a barrier, and the reference teaches that hybridization with different samples requires separation (page 571, last paragraph). The reference does not specifically teach physical barriers for keeping the arrays and/or probes in corresponding arrays. However, physical barriers grooved and/or hydrophobic were well known in the hybridization art at the time the invention was made as taught by Kauver and Wang.

Kauver teaches an array of reaction regions on a solid support, each region having a plurality of ligands immobilized in the region wherein the regions are separated by a hydrophobic barriers (Column 7, lines 39-45) whereby reactions within the regions are defined thereby simplifying interpretation of assay results (Column 4, lines 37-58). Wang also teaches an array of reaction areas separated by hydrophobic barriers whereby cross-contamination is virtually eliminated and an "excellent appearance of the final product" is obtained (Column 4, lines 22-53).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the physical separation of Wang and/or Kauver to the multiple arrays of Drmanac. One of ordinary skill in the art would have been motivated to do so, with a reasonable expectation of success, for the expected benefit

obtaining clearly defined assay results as is well known and routinely practiced in the art of bio-assays (Kauver, Column 4, lines 37-58 and Wang, Column 4, lines 22-53).

Regarding Claims 159 and 169, Drmanac teaches the support wherein the microchips are arranged in multiple rows and columns (Fig. 4). And Kauver teaches the arrays in an orderly design pattern" (Column 4, line 60) and Wang teaches the similar support comprising multiple rows (Fig. 1).

Regarding Claims 160,170, 183 and 189 Drmanac teaches the support wherein the microchips are "positioned" for use with a multichannel pipette (i.e. arrayed, Fig. 4).

Regarding Claim 161 and 171, Drmanac teaches hybridization reagents (page 571). Hardy teaches the similar support and hybridization reagents (Column 11).

Regarding Claims 162 and 172, Drmanac teaches the arrays are arrayed in 8 by 12 format (paragraph spanning pages 569-570).

Regarding Claims 163 and 173, Drmanac teaches the support wherein the array of microchips comprises more than 256 probes (page 569-570).

Regarding Claims 164 and 174, Drmanac teaches the support wherein the probes of between 4 and 9 bases are spotted onto the arrays for hybridization (page 571).

Regarding Claims 165 and 175, Drmanac teaches the support of Claims 97 and 166 as discussed above. While the reference does not teach light-directed synthesis. However, the courts have stated that "even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of

production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) see MPEP 2113. Because determination of patentability is based on the product and because the combination of Drmanac and Hardy teach the product, the process of making the product as recited in the claim does not define the product over the prior art.

Regarding Claims 184-185 and 187-188, Drmanac teaches the support has duplicate arrays thereby providing arrays that are identical to other arrays, but different from others (Fig. 4 and accompanying text).

Conclusion

9. No claim is allowed

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (571) 272-0741. The examiner can normally be reached on 6:00 TO 3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen can be reached on (571) 272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BJ Forman
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